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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/592,908 | 07/17/2008 | Jason R. Sullivan | CRD5080USPCT | 4781 |
| 27777 | 7590 | 10/06/2011 | EXAMINER | |
| PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003 | | | EVERAGE, KEVIN D | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3734 | |
| | | | NOTIFICATION DATE | DELIVERY MODE |
| | | | 10/06/2011 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/592,908 | Applicant(s) SULLIVAN ET AL. | |
| | Examiner KEVIN EVERAGE | Art Unit 3734 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1,2 and 4-7 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1,2 and 4-7 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 29, 2011 has been entered.

Response to Amendment

2. Applicant's amendment filed July 29, 2011 is fully considered. Claims 3 and 8 are cancelled. Claims 1, 2 and 4-7 are currently pending and under consideration.

Claim Objections

3. Claims 1, 2 and 4-7 are objected to because of the following informalities:

There is a spelling error in line 13 of claim 1 ("medial" filter). Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. **Claims 1, 2 and 4-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

Claim 1 recites the limitation "the medial filter" in line 13. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. **Claims 1, 2 and 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bosma et al. (US 6,443,972) in view of Greenhalgh (US 6,364,895) and Weaver (US 2004/0186510 A1).**

Bosma et al. ("Bosma") a medical filter for therapeutic treatment of a patient comprising:

a first and second end (see Figure 8, unlabeled) defining a longitudinal axis;
a plurality of struts (defining passages 25) extending between the first and second ends, the struts tending to resiliently expand in radially outward directions from a compressed initial shape to an expanded deployed shape (see column 3, lines 34-40);
wherein in the expanded deployed shape, the struts define a first and second filter section and a center section connecting the filter section (first and second sections

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surround center section, labeled by ref. 24), the center section comprising longitudinally oriented struts (24);

wherein each of the first and second filter sections define a number of filter cells (see Figure 8);

the medical device being configured for retrievable implantation within a vessel (see column 7, line 51 - column 8, line 5); and

the medical filter having its elements cut from a single tubular metal element (see Figures 6 and 8; see column 5, lines 42-65) for implantation within a patient (see column 7, line 51 - column 8, line 5), the medical filter being completely detachable from its delivery system during deployment (see column 3, lines 34- 40). The claimed phrase "cut from a single tubular metal element" is being treated as a product by process limitation. As set forth in MPEP 2113, product by process claims are not limited to the manipulation of the recited steps, only the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 USC 102/103 rejection may be made and the burden is shifted to applicant to show an unobvious difference. MPEP 2113.

While Bosma fails to disclose the second filter section defining a greater number of filter cells than the first section, Greenhalgh discloses a vascular filter which has a second filter section with a greater number of filter cells than a first section (see Figure 1). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the higher- density filtering in the second section, as disclosed by Greenhalgh, in the device of Bosma in order to provide a greater filtering efficiency,

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allowing particles to flow into the filter through the first portion but retaining those particles in the denser second portion (see Abstract). Bosma discloses recapturing the apparatus using a "cord body" (see column 7, line 51 - column 8, line 5), but fails to disclose a recapture hook structure with a symmetrical configuration for removal of the medial filter positioned on at least one end. However Weaver discloses that the use of a hook structure (26) with a symmetrical configuration about a longitudinal plane bisecting the hook (see Figure 2) for removal of an embolic filter is known in the art (see Paragraph 18). It would have been obvious to someone of ordinary skill in the art at the time of the invention to equip the filtering apparatus disclosed by Bosma with a hook structure attached to the cord body at one end for quick and easy retrieval in light of Weaver's disclosure.

Regarding claim 2, the arrow in Figure 1 of Greenhalgh indicating the direction of blood flow shows that the first section is upstream of the second.

Regarding claim 4, the filter is usable in the vena cava.

Regarding claim 5, Figure 8 discloses anchors (26, 27) formed on at least one surface of the filter, and Figures 9A-9C show a closer view of various embodiments of such anchors.

Regarding claim 6, the central portions of the struts extend parallel to the

longitudinal axis (see Figure 8).

Regarding claim 7, Bosma discloses the filter being made of nitinol (see column 4, lines 11-14).

Response to Arguments

8. Applicant's arguments filed July 29, 2011 have been fully considered but they are not persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In response to applicant's argument that there is no teaching, suggestion, or motivation to combine the references, the examiner recognizes that obviousness may be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988), *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992), and *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007). In this case, Greenhalgh discloses that the open upstream section allows for unrestricted flow of

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blood into the denser downstream section which filters the blood (see column 4, lines 32-35 and column 5, lines 25-48). This provides a motivation to modify the symmetrical filter cells that are of equal size disclosed by Bosma to be asymmetrical.

Regarding adding a retrieval hook to the Bosma apparatus: Bosma already discloses a need for retrieving the implant using a "cord body" (see column 7, line 51 - column 8, line 5). Weaver then discloses that a recapture hook is an equivalent, known structure in the art of retrieving a filter body and it would have been obvious to one of ordinary skill in the art at the time of the invention to include a recapture hook with the Bosma apparatus as an alternative mechanism of retrieving the filter.

In response to applicant's argument that there is no reason to have combined the references without using the claimed invention as a template, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In the present case, the references would suggest that a denser strut configuration at the downstream section of the Bosma apparatus would allow for more efficient blood filtering while leaving the proximal section more open to facilitate blood flow into the denser end.

Conclusion

9. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin Everage whose telephone number is (571) 270-7485. The examiner can normally be reached on Monday to Friday from 10 am to 6 pm.

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If attempts to reach the examiner by telephone are unsuccessful, ***please contact the examiner's supervisor, Gary Jackson, at (571) 272-4697***. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to

TC3700_Workgroup_D_Inquiries@uspto.gov.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/K.E./

/Gary Jackson/
Supervisory Patent Examiner
Art Unit 3734
September 29, 2011